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(54) Title: DEMAND POSITIVE PRESSURE AIRWAY SYSTEM FOR APNEA TREATMENT

(57) Abstract

A respiratory system for overcoming an airway obstruction or restriction by a demand positive airway pressure arrangement wherein any change in airway patency in a patient causes a constant air flow to be diverted from the patient to a sensor located downstream in an airflow line which also is in communication with the patient. The sensor signals a positive increase in airway flow rate to blow open the patient's obstruction/restriction, thereby re-directing the air flow from said sensor back to normal into the patient's lungs, and thereafter, returning the airflow blower/generator to its lower normal flow rate.

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DEMAND POSITIVE PRESSURE AIRWAY SYSTEM FOR APNEA TREATMENT

Background of the Invention

(1) Field of the Invention

This invention relates to devices for applying air pressure to unblock blocked or restricted air passageways and for the treatment of sleep apnea.

(2) Prior Art

As many as three percent of the population suffers from a disorder called sleep apnea, a condition whereby the soft tissues of the throat obstruct breathing during sleep. People who suffer with this problem may become awaken as many as three hundred times a night. They never reach a deep REM sleep, thereby never getting enough proper rest, creating dangerous fatigue which can lead to auto accidents, other problems or death.

Brief Summary of the Invention

The present invention involves a demand positive airway pressure system for opening an obstructed or restricted air passageway such as the pharynx or throat of a patient. This demand positive airway pressure system comprises an open loop with a motor driven blower unit with an air intake port or oxygen delivery source to deliver a constant flow of air to a patient until a respiratory problem of a patient is sensed on a breath by breath basis and adjusts the airflow rate accordingly. The blower unit is powered by a rapid ramp up

and ramp down electric motor. The blower unit has an output port which is in fluid flow communication with a nasal mask through a wide bore delivery tubing.

The nasal mask is adapted to fit in a snug arrangement about the nose of the patient. A sensor conduit is in communication with the nasal mask and provides fluid communication with the mask and a fluid flow rate sensor device. The sensor conduit continues downstream of the flow rate sensor device, through a flow regulator valve, and thence to the atmosphere.

The flow rate sensor device has an output signal which is communicated to a microprocessor unit. The microprocessor unit controls the speed of the electric motor and may signal an audible alarm when a dangerous condition is detected. A control switch device sets the limits of the speed range and operating parameters of the microprocessor unit.

In operation, the demand positive airway pressure system delivers a constant, relatively low flow rate of air to a patient who is wearing the nasal mask.

The patient breathes normally, both inhaling and exhaling at a normal rate. Should the patient develope an abnormal blockage, apnea or restriction, the normal air flow into the patient's lungs during the normal breathing cycle gets otherwise diverted into the sensor conduit which is also in fluid communication with the patient at the nasal mask.

The increased flow rate diverted from the mask is quickly picked up by the flow rate sensor as outflow into the sensor conduit, above the normal respiration level, the flow rate sensor being in communication with the sensor conduit. The flow rate sensor sends an electrical signal to the microprocessor controlling the blower motor empowering the blower to ramp up the flow rate therefrom, to force an above normal flow rate through the wide bore delivery tubing, thus forcing whatever larger volume of air that is necessary into the nasal mask and hence the patient's pharynx/airway, blowing open the restriction/obstruction and permitting the patient normal inspiration and expiration once again.

As soon as the obstruction is overcome or eliminated, the higher flow rate of air is driven into the patient's airways and not through the sensor conduit. The flow rate sensor downstream in the sensor conduit immediately picks up the dimunition in flow rate therethrough, sending a further signal to the microprocessor, to immediately slow down the blower motor and the blower to their lower pre-selected flow rate levels as determined by the patency of the airway, to await further rate changes, as necessary.

The flow balancer at the distal end of the sensor conduit, downstream of the flow rate sensor is a gate valve, is adjustable, so as to permit a pre-selected rate of flow of air therethrough to accommodate the particular patient's

respiration rate. The flow rate for each individual is different, because of lung capacity, age, pulmonary function and the like. Therefore, individual flow rates are set so as to not inadvertently trigger an improper signal from the flow rate sensor. When a blockage or restriction in the patient's airway does occur, this lower level restricted flow pre-set in the flow balancer is swamped by the flow diverted from the delivery conduit, thus setting off the flow rate sensor signal.

The invention thus includes a respiratory system for overcoming an airway obstruction in a patient connected to said system, comprising: an electrically empowered airflow generating means arranged to deliver a constant flow of air to a patient until an airway obstruction/restriction is detected; a delivery conduit in communication with the airflow generating means; a face mask attached to the delivery conduit, the delivery conduit having a pair of channels therewith, one of the channels delivering a flow of air to the mask, another of the channels returning a flow of air to a flow rate sensor, for determining irregular conditions with respect to the mask and a patient wearing the mask. A vacuum comparator device is also in fluid communication with the delivery conduit and the flow sensor. The vacuum comparator is arranged to receive and determine any excess flow rate from the airflow generating means, to

trigger a valve to dump any excess flow into the atmosphere. An audible alarm which is triggered by an irregular condition of the mask or opening of the flow conduits, as sensed by the flow rate sensor. A power-off alarm which is arranged in electrical communication with the airflow generating means, to generate an audible alarm which is triggered by an electrical supply failure empowering the airflow generating means or to sense cessation of normal breathing effort of a patient, indicating a condition known as central apnea. A method for providing relief for an airway problem in a patient, using a portable electronic respiratory system of the present invention comprises the steps of: providing an electrically empowered airflow generating means; arranging a delivery conduit for flow of fluid air from the generating means to a patient; arranging a mask on the end of the delivery conduit, for wearing by a patient; delivering a relatively constant and continuous flow of air from the airflow generating means; returning a flow of air from the mask through a separate channel in the delivery conduit, to a flow sensor so as to trigger a response when any irregular event is sensed within the electronic respiratory system; sensing the flow rate returning in the separate channel; increasing the flow rate of air coming from the airflow generating means and into the mask if the flow sensor senses an increase in flow in the separate channel, so as to

overcome an obstruction or restriction in the airway of a patient wearing the mask; triggering an alarm so as to signal a loose mask or open circuit on a patient, creating an air loss and a decrease of air flow returning through said return channel;triggering an alarm powered by a separate battery in the electronic respiratory system if there is a power failure within the system.

Brief Description of the Drawings

The objects and advantages of the present invention will become more apparent when viewed in conjunction with the following drawing, in which:

Figure 1 is a schematic representation of the airway system according to the present invention; and

Figure 2 is a representation of the circuitry of the present invention.

Description of the Preferred Embodiments

Referring now to the drawings in detail, and particularly to figure 1, there is shown a schematic representation of a demand positive airway pressure system 10, which is utilized to show a device useful for opening an obstructed or restricted air passageway such as the pharynx or throat of a patient.

This demand positive airway pressure system 10 comprises an open loop cycle, with a blower unit 12 having an air intake port 14 or oxygen source. The blower unit 12 is

rotatively powered by a variably adjustable electric motor 16 capable of rapid ramp up and ramp down. The blower unit 12 has an output port 18 which is in fluid flow communication with a nasal mask 20 through a wide bore delivery conduit 22. The delivery conduit 22, common in the field, is about 3/4 of an inch in diameter.

The nasal mask 20 is arrangable to fit snugly about the nose of a patient P. The delivery conduit 22 also includes an extension of a sensor conduit 26 therewithin. The sensor conduit 26 has a downstream end which connects to a critical fluid flow rate sensor device 28 such as a Honeywell Microswitch flow sensor Model No. AWM-3300V. The sensor conduit 26 provides fluid communication between the nasal mask 20 and the fluid flow rate sensor 28. A sensor conduit extension 30 may be arranged on the downstream side of the fluid flow rate sensor 28. The sensor conduit extension 30 may be connected to a flow balancer valve 32, such as a Dwyer brand valve. The valve 32 has a discharge port 34 open to the atmosphere. The sensor conduit 26 in a further embodiment, could be coaxially arranged in the delivery conduit 22, for ease of patient movement, the downstream end of the sensor conduit 26 exiting out through the sidewall of the delivery conduit 22, at a location within the housing 25.

The fluid flow rate sensor 28 in either embodiment, is in electrical commmunication, through a proper circuit 36, to

a microprocessor speed control unit 38. The speed control unit 38 is in electrical communication, through circuit 40, to the motor 16. A control switch 42 is in electrical communication with the speed range, voltage and operating parameters such as rise time, fall time and min/max voltage for the motor 16 and blower unit 12.

In the operation of the demand positive airway pressure system 10, a constant flow rate of air is delivered at a rate to approximately 3cm of water pressure, to a patient P who is wearing the nasal mask 20.

The patient breaths normally, both in inspiration and expiration. Should the patient develope an abnormal blockage (apnea) or restriction in his throat, airway or pharynx, the air flow which generates pressure typically at about 2 to 3 cms of water, is prevented from going into the patient's airway and is diverted into the sensor conduit 26. The flow rate thus coming from the delivery tube 22, though at a low and balanced rate, is higher than would be expired by the patient during normal breathing.

The sensor conduit 26 thus directs this sudden increase in flow rate of air, into the flow rate sensor 28. The flow rate sensor 28 detects this increase in flow rate and sends an electrical signal to the microprocessor speed control unit 38. The speed control unit 38 in turn sends a signal to the motor 16 to ramp up the flow rate output into the delivery

conduit 22 to force a sudden larger flow of air into the patient's airway from the nasal mask 20, blowing open or alleviating the obstruction in the patient's throat or pharynx, and permitting the patient normal inspiration into his lungs, thereby also dropping the ramped-up flow rate in the sensor conduit.

As the obstruction of the airway of the patient P is overcome, the flow rate sensor 28 thereby automatically senses the diminution in flow rate through the sensor conduit 26. The flow rate sensor 28 then sends a further signal to the microprocessor speed control unit 38, which immediately signals the motor 16 to ramp down the flow rate through the delivery conduit 22, thus returning the system 10 to its normal constant low rate of air therethrough, awaiting further "ramp-ups" as necessary, should a further apnea or airway obstruction occur in the patient connected to the system 10.

The flow balancer valve 32 at the downstream end of the sensor conduit extension 30 acts as a flow restrictor or gate valve to balance the normal expiration of the patient. It is adjustable so as to permit changes in back pressure to the flow rate of air being ejected out the discharge port 34. The balancer valve 32 is necessary to permit individual patients who use the system 10, to set their own flow rate since their own inspiration, expiration and lung capacity are

different from other peoples flow rate. The balancer valve 32 thereby prevents false signals from being sent from the flow rate sensor 28 if too much air came through the particular conduits 26 and 30 without any back pressure.

A further embodiment of the respiratory system is shown in figure 2, wherein respiration of the patient is detected by the use of a small diameter tube 67 connected to a face mask 52 as shown in figure 2. This tube 67 is attached to a port of a flow sensor 54 located within the system. The flow sensor 54 has an electrical output which is an analog voltage that is proportional to the flow of air passing through the sensor 54. This voltage varies from 0 volts to approximately 8 volts D.C. The output voltage of the sensor 54 is then directed to the non-inverting input of a voltage comparitor circuit 56, such as an operational amplifier that is being utilized as a voltage comparator. This voltage comparator 56 is biased by an 8 volt power supply 58. The comparator voltage is adjusted by the use of a voltage divider network utilizing a multi-turn potentiameter 60. If the blower 62 (which has an output control 63) operates at its minimum speed and the mask 52 is occluded, the available air from the blower 62 is directed to the sensor 54. It is in this condition that the voltage divider 60 is adjusted for the point where the output of the comparator 56 just switches to a high state. This sets the calibration of the voltage

comparator 56 portion of the system.

As shown in figure 2 in an exemplary manner, the output of the comparator 56 is now directed to one input of a dual input NAND Gate 64. The second input to this gate is derived from the output of a timer integrated circuit 66. The output of this timer 66 is directed to the input of a NOR Gate 68. The second input of the NOR Gate 68 is derived from a second timer 70 which establishes the demand delay (preset) time to permit a patient tp reach a sound level of sleep before a signal will be triggered. The timer 66 is utilized to establish the delay time for the increase of the speed of the blower 62. A time selector network 72 allows an operator to select a demand time. Timing is controlled by the use of a capacitor 74 in communication with a multi-turn potentiometer 76. Potentiometers 85 and 87 are in communication with timer 66, as shown in figure 2. The timer 66 starts its cycle when the output of the comparator 56 goes high. This high output is directed to the trigger of the timer 66through the capacitor 74. This capacitor 74 allows the trigger input of the timer 66 to go high for a very short duration of time and then return to a low state even though the output of the comparator 56 remains high. The reset terminal of the timer 66 is connected directly to the output of the comparator 56 and will cause the timer 66 to reset when the voltage level of the sensor 54 drops below the set level of the comparator

56. This enables the circuit to reset itself once an occlusion in an airway of a patient wearing the mask 52 is overcome, by driving the input ot the timer 66 of the NOR Gate 68 to a low level.

The output of this NOR Gate 68 is inverted by the use of another NAND Gate 78 and then directed to the base of a transistor in a switching circuit 80. The emitter of this transistor is grounded and a solid state relay within the switching circuit 80 is connected in series with the collector of the transistor to the voltage from the power supply 58. A potentiometer 82 is used to adjust the low speed of the blower 62 and another potentiometer 84 the high speed of the blower 62.

When an occlusion occurs, maximum air flows through the sensor 54 from the mask 52 through the sensor conduit 67. The output voltage of the sensor 54 then exceeds the threshold voltage of the comparator 56. After a pre-determined period of time (determined by the timer circuit 66), the transistor within the switching circuit 80 goes into saturation, causing the blower 62 to ramp up to a higher speed from its typical constan level, thus increasing the flow of air to the patient through the delivery tube 59.

After the occlusion is overcome, air enters the patient's lungs and less air is directed through the sensor 54. Thus, the output voltage of the sensor 54 then drops

below the set threshold of the comparator 56 causing the output of the comparator 56 to go to a low state. This low state resets the timer 66 and ultimately turns off the transistor within the switching circuit 80. The switching circuit 80 then causes the blower 62 to ramp down to its lower constant level of airflow generated therefrom. Thus the blower 62 is then in the low constant level output state and the circuit is now in a standby condition waiting to detect another occlusion.

The negative flow input 88 of the flow sensor 54 is connected to atmosphere through a vacuum comparitor 90. This vacuum comparitor 90 establishes a maximum flow level through the sensor 54 so that the sensor 54 will not become saturated when the airflow generating blower 62 is operating at its maximum airflow rate.

The system contains a plurality of alarm circuits. A first alarm 92 monitors the line power into the unit and emits and audible alarm whenever an interruption of power is detected. When the power switch 94 is in the "on" position, a battery, not shown, is connected to the normally closed contacts of an alarm switching circuit 95. If there is no power applied to the unit or if there is a fault with the power supply, an annunciator 96 will sound. If there is power to the unit and power supply 58 if functioning properly, the alarm switching circuit 95 will be disconnect

the annunciator 96 from the circuit. Anytime there is an interruption of power and the power switch 94 is in the "on" position, the alarm will sound.

A second alarm circuit 98 detects if there is a leak within the pneumatics of the system. The output of the flow sensor 54 is connected to another comparator circuit within the alarm circuit 98. Whenever any air flow is detected through the sensor 54, a voltage is applied to the input of the alarm circuit 98. The electrical output of the comparator 54 is high when air flow is present. This high electrical output keeps the alarm circuit 98 off. When airflow is interrupted, the electrical output of the comparitor 54 is low and triggers the alarm switching circuit 98, causing the annunciator 96 to sound. A further alarm indicates central apnea.

Thus, what has been shown and described in a unique demand positive airway pressure system is a low flow rate delivery of inspiratory directed air utilized to monitor and correct a patient on a breath to breath basis, which, when diverted by an obstruction or restriction in the airway of the patient from entering that patient's lungs, is directed to a flow rate sensor which detects the need for a higher delivery rate, to "blow open" the obstruction or restriction, thus opening the airway to the lungs, and once the obstruction or restriction is alleviated, the flow rate being

sensed at the flow rate sensor valve immediately drops, which signals the blower unit to a slower normal flow rate to the benefit and comfort of the patient attached to the system.

CLAIMS :

1. A respiratory system for overcoming airway obstruction on demand, in a patient connected to said system, comprising:

an air flow generating means;

a delivery conduit in communication with said air flow generator and a mask worn by a patient to direct a constant rate of floe of air from said air flow generatimg means to the patient; and

a flow sensing means in communication with said mask arranged to rapidly change the flow rate of air from said constant rate from said air flow generating means upon the detection of a change in the airway of the patient wearing said mask.

2. A respiratory system as recited in claim 1, including a flow rate balancing valve in communication with said flow sensing means to permit adjustability of back pressure in said system to accommodate variations in the expiration rate of any patient wearing said system.

3. A respiratory system as recited in claim 2, including a means for controlling the rate of flow from said air flow generating means as sensed by said flow sensing means.

4. A respiratory system as recited in claim 1, wherein said constant rate of air flow directed to said mask is increased upon the detection of back pressure from a patient wearing said mask.

5. An apnea overcoming respiratory system to permit a

patient using said system to reach a full deep sleep, the system comprising:

an air flow generating means for generating a constant flow of air to a patient;

an air flow directing means securable to the patient using said system;

an expiratory conduit arranged to sense changes in the flow rate therethrough; and

signal generating means responsive to change, in said expiratory conduit so as to change the rate of air flow coming into said airflow directing means from said air flow generating means, upon detecting of an apnea event.

6. An apnea overcoming system as recited in claim 5, wherein said signal generating means includes an airflow rate sensing valve which is in fluid communication with said airflow directing means.

7. An apnea overcoming system as recited in claim 6, wherein said airflow directing means includes a nasal mask and an air conduit from said air flow generating means to said mask.

8. An apnea overcoming system as recited in claim 6, wherein said airflow sensing means permits the monitoring of a patient's respiration on a breath by breath basis, so as to permit a ramping up of airflow from a preset constant level on demand, and a ramp down of airflow rate to said preset level upon removal of the obstruction from the airway of a

patient using the system.

9. An apnea overcoming system as recited in claim 8, wherein said airflow directing means includes a delivery conduit, said delivery conduit having said expiratory conduit therewithin for facilitating movement of a patient therewith.

10. A respiratory system for overcoming an airway obstruction on demand, on a breath by breath basis, comprising:

a constant low level flow rate air supply to a patient using said system;

a sensor conduit and a sensing switch arranged therein, to sense a restriction in the airway of a patient;

means in communication with said switch for increasing the air supply flow rate from said constant low level air flow rate to a higher air flow rate upon the sensing of a patient with a restricted airway, said means also arranged to decrease the increased flow of the air supply to a patient upon said sensing switch sensing no further patient airway restrictions.

11. A respiratory system as recited in claim 10, including a balancing valve arranged in the downstream end of the sensor conduit to permit adjustability of backpressure therein to a patient's normal expiration to prevent missoperation.

12. A respiratory system for overcoming an airway obstruction or restriction in a patient connected to said system, comprising:

an electrically empowered airflow generating means arranged to deliver a constant flow of air to a patient until an airway obstruction/restriction is detected;

a delivery conduit in communication with said airflow generating means;

a face mask attached to said delivery conduit, said delivery conduit having a pair of channels therewith, one of said channels delivering a flow of air to said mask, another of said channels returning a flow of air to a flow rate sensing arrangement, for determining irregular conditions with respect to said mask and a patient wearing said mask.

13. A respiratory system as recited in claim 12, including a vacuum comparator device which is also in fluid communication with said delivery conduit and said flow sensor.

14. A respiratory system as recited in claim 13, wherein said vacuum comparator device is arranged to receive and determine any excess flow rate from said airflow generating means, to to dump any excess flow into the atmosphere.

15. A respiratory system as recited in claim 13, including an audible alarm which is triggered by an irregular condition of said mask, as sensed by a flow rate sensor of said sensing arrangement.

16. A respiratory system as recited in claim 13, including a power-off alarm which is arranged in electrical communication with said airflow generating means, to generate an audible alarm which is triggered by an electrical supply failure empowering said airflow generating means.

17. A respiratory system for overcoming an airway obstruction in a patient connected to said system, comprising:

an electronically empowered airflow generating means for generating a constant low level flow of air to a patient;

a delivery conduit in communication with said airflow generating means;

a face mask attached to said delivery conduit for directing airflow to a patient;

a sensor arrangement in communication with said delivery conduit to detect any resistance to airflow in a patient; and

means to increase the rate of airflow in said delivery conduit from said constant low level floe of air upon said sensor arrangement detecting any airflow resistance, to overcome any resistance encountered.

18. A face mask in communication with a respiratory airflow generator which is arranged to generate a constant airflow to a patient, arranged for overcoming an obstruction in an airway of a patient wearing said face mask, upon the sensing of an obstruction or restriction in the airway of a patient, said mask including;

a flow rate sensor arranged in communication with said face mask to monitor the flow of air from said airflow generator to said face mask and airflow from said face mask to said airflow generator.

19. A respiratory system for diagnosing and overcoming an apnea event in a patient connected to said system, comprising:

an airflow generating means for generating a constant level of airflow to a patient until the sensing of an apnea event in a patient;

a fluid conduit and mask to communicate air flow with said generating means and a patient thereattached, said fluid conduit directing a constant level of airflow from said generating means to a patient, and from a patient to a flow sensor means also in fluid communication with said conduit; and

said sensor arranged to detect an apnea event and to trigger a responsive succession of higher flows of air from said constant level, to a patient so as to overcome that apnea event.

20. A respiratory system as recited in claim 19 wherein said fluid conduit has a common lumen for directing airflow to a patient and for directing a change in airflow to said sensor from a patient, so as to trigger apnea overcoming responsive flow of air to that patient.

21. A respiratory system for diagnosing and overcoming an apnea event in a patient communicating with said system, comprising:

an airflow generating means arranged to create a constant level regulatable flow of air;

a conduit and breathing mask in communication with said airflow generating means, for attachment to a patient;

a sensor for detecting a blockage to a flow of air in the patient wearing the mask;

a means for signaling said generating means to ramp-up the flow of air from a first constant flow rate to an increased flow rate, upon the detecting by said sensor, of an apnea event;

means for signaling said generating means to ramp-up the flow of air from said second flow rate to a further increased air flow rate for a predetermined minimum time to insure inspiration of the patient wearing said mask, and subsequently signal said generating means to return the flow rate in said conduit, to a lower constant level air flow rate.

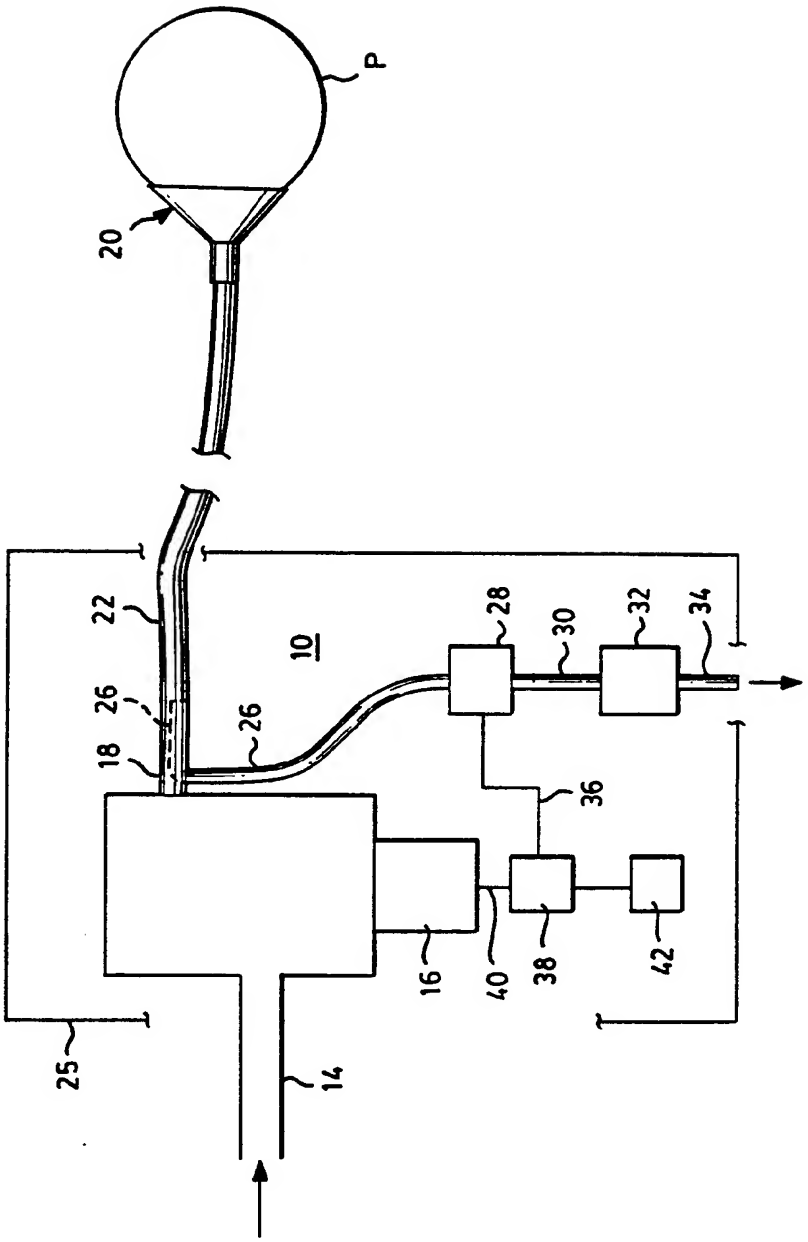

FIG. 1

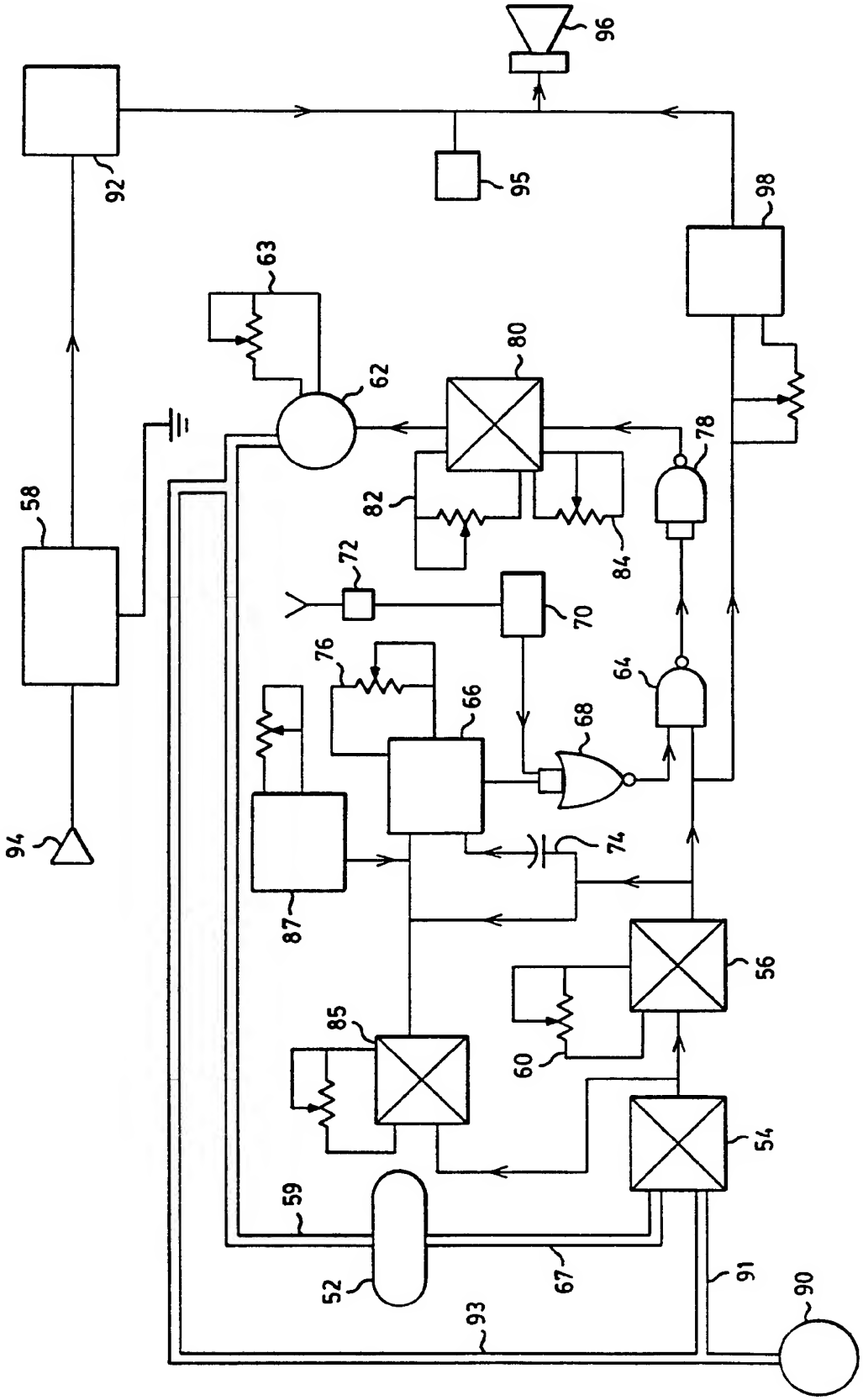
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FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/05095

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 15/08, 16/00; A62B 7/00, 7/04, 9/00; F16K 31/02; A62B 9/04;
US CL :128/204.18, 204.21. 204.23. 204.26, 202.27, 205.23, 207.18
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/204.18, 204.21. 204.23. 204.26, 202.27, 205.23, 207.18, 716, 719

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P ----- Y,P	US, A, 5,199,424 (SULLIVAN ET AL) 06 APR 1993. SEE THE ENTIRE DOCUMENT.	1,4,5,10, 12,17-21 ---------- 2,3,5-9,11, 13-16
X,P -------- Y,P	US,A, 5,148,802 (SANDERS ET AL) 22 SEP 1992. SEE THE ENTIRE DOCUMENT.	1,5,10,12, 17-21 ---------- 2-4,5-9,11, 13-16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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23 August 1993

Date of mailing of the international search report
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